AMENDED IN ASSEMBLY APRIL 5, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL

No. 2300

Introduced by Assembly Member Emmerson

February 18, 2010

An act to add Chapter 10.7 (commencing with Section 4700) to Division 2 of the Business and Professions Code, and to amend Sections 124980 and 124996 of, and to repeal Section 124981 of, the Health and Safety Code, relating to genetic counselors, and making an appropriation therefor. An act to add Section 124982 to the Health and Safety Code, relating to genetic counselors.

LEGISLATIVE COUNSEL'S DIGEST

AB 2300, as amended, Emmerson. Genetic counselors.

Existing law, the Hereditary Disorders Act, requires the state State Department of Public Health to establish hereditary disorder programs, 100 specified, and to license master level genetic counselors and doctoral level geneticists. One of the requirements for licensure is that an individual demonstrate competence by a examination administered or approved by the department. Existing law prohibits an unlicensed person from using the title of genetic counselor. Existing law provides for the licensing and regulation of various healing arts practitioners by regulatory boards in the Department of Consumer Affairs.

This bill would create the Genetic Counselors Licensing Board in the Department of Consumer Affairs, which would consist of 7 members appointed by the Governor. This bill would specify the powers and duties of the board relative to licensing and regulation of genetic counselors, as defined, and would, on and after July 1, 2011, prohibit any person from engaging in the practice of genetic counseling without

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a license issued by the board. The bill would authorize the board to establish licensure fees to be deposited in the Genetic Counselors Fund, which would be created by the bill. Moneys in the fund would be continuously appropriated to the board for purposes of the act.

This bill would require, on and after July 1, 2011, the department to issue a temporary genetic counselor license, valid for one year, to a person who meets all of the requirements for licensure except passing the above-described examination. The bill would require a person working under a temporary genetic counselor license to work under the general supervision of a licensed genetic counselor or a licensed physician and surgeon.

Vote: majority. Appropriation: yes-no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 124982 is added to the Health and Safety 2 Code, to read:

124982. (a) On and after July 1, 2011, the department shall issue a temporary genetic counselor license valid for one year to a person to practice genetic counseling who meets all the requirements for licensure set forth in Section 124981, except passing the certification examination as required by Section 124981.

- (b) A person holding a temporary genetic counselor license who fails the first available certification examination held by the ABGC may reapply, no later than 30 days after the date of the examination, on a one-time basis, for an additional temporary genetic counselor license.
- (c) Notwithstanding subdivision (a), a temporary license issued pursuant to this section shall expire upon any of the following events, whichever occurs earlier:
 - (1) The issuance of a license pursuant to Section 124981.
- (2) Thirty days after notification of the department that an applicant has failed the certification examination, or on the date that the applicant applies and is granted an additional temporary license pursuant to subdivision (b).
- (3) The expiration date on the temporary license.
- 23 (d) A person holding a temporary genetic counselor license 24 issued pursuant to this section, shall be required to work under

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the general supervision of a licensed genetic counselor or a licensed physician and surgeon.

SECTION 1. Chapter 10.7 (commencing with Section 4700) is added to Division 2 of the Business and Professions Code, to read:

CHAPTER 10.7. GENETIC COUNSELORS

- 4700. (a) There is in the Department of Consumer Affairs a Genetic Counselors Licensing Board. The board consists of seven members, five of whom shall be licensed in accordance with this chapter or as provided in subdivision (g) and two of whom shall be public members. The members of the board shall be appointed by the Governor to serve a term of two years. No member shall be appointed to serve more than two consecutive terms, provided that a member appointed to fill a vacancy may serve for the time remaining in that term plus be appointed to two additional terms. A former member may be reappointed pursuant to this section after a two-year period of nonservice following his or her serving two terms. Members shall be residents of this state.
- (b) A member may be removed by the Governor for neglect of duty, misconduct, or misfeasance in office upon provision of written notice of the charges against the member and an opportunity to be heard. Upon the death, resignation, or removal for cause of a member, the Governor may fill the vacancy for the remainder of the member's term.
- (c) The board shall, at its first meeting and annually thereafter, organize by electing from its members a chair, vice chair, and secretary. Those officers shall serve until their successors are elected and qualified.
- (d) The board shall meet at least twice annually, and may hold additional meetings at the call of the chair or at any time as may be determined by the board.
 - (e) The board shall do all of the following:
- (1) Adopt rules and regulations necessary to license and regulate genetic counselors.
 - (2) Recommend policy and budgetary matters to the department.
- (3) Establish administrative procedures for processing applications for licenses and renewals, and license reinstatements.

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1 (4) Hire or appoint staff or agents, as appropriate, for processing applications.

- (5) Retain records of its actions and proceedings.
- (6) Conduct hearings.

- (7) Impose discipline on licensees for violations of this chapter and rules and regulations adopted pursuant thereto, including fines, censures, reprimand, placement on probation, and license revocations, suspensions, and denials.
- (8) Summarily suspend the license of a licensee who poses an imminent danger to the public.
- (9) Maintain rosters of the names and addresses of licensees and all persons against whom adverse license action has been taken. These rosters shall be available to the public upon written request and payment of a fee set by the board.
- (10) Perform any other functions as may be required to carry out this chapter.
- (f) Members of the board shall serve without compensation but may be reimbursed for actual and reasonable expenses incurred in the performance of their duties.
- (g) The five seats on the board to be held by licensees shall initially be held by genetic counselors who are certified by the American Board of Genetic Counseling and who otherwise meet the requirements for licensure set forth in Section 4701 or genetic counselors who, as of January 1, 2011, are licensed pursuant to Section 124981 of the Health and Safety Code.
- 4701. (a) (1) On and after July 1, 2011, no person may engage in the practice of genetic counseling or use the title of genetic counselor unless he or she has obtained a license issued by the board pursuant to this chapter.
- (2) "Genetic counseling" means the process by which patients or relatives, at risk of an inherited disorder, are advised of the consequences and nature of the disorder, the probability of developing or transmitting the disorder, and the options open to them in management and family planning in order to prevent, avoid, or ameliorate the disorder. Genetic counseling includes activities carried out pursuant to the Hereditary Disorders Act, as defined in Section 27 of the Health and Safety Code.
- (b) The board shall issue a license to an applicant who does or has done all of the following:

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(1) Has earned a master's degree or above from a program specializing in or having substantial course content in genetics.

- (2) Passes the certification examination administered by the American Board of Genetic Counseling (ABGC).
- (3) Has completed a genetic counseling program accredited by the ABGC.
- (4) Has been granted, and maintains, active candidate status by the ABGC.
- (5) Files an application with the board, including a letter of recommendation signed by a supervisor of the applicant.
- (6) Pays a licensure fee as determined by the board pursuant to Section 4704.
- (c) Notwithstanding subdivision (b), the board shall issue a license to an applicant who, on January 1, 2011, holds a genetic counselor license issued by the State Department of Public Health pursuant to Section 124981 of the Health and Safety Code.
- 4702. (a) A genetic counselor license shall be valid for three years unless at any time during that period it is revoked or suspended. The license may be renewed prior to the expiration of the three-year period.
- (b) To qualify to renew the license, the licensee shall have completed 45 hours of continuing education units during the three-year license renewal period. At least 30 hours of the continuing education units shall be in genetics.
- 4703. (a) On and after July 1, 2011, the board shall issue a temporary genetic counselor license valid for one year to a person to practice genetic counseling who meets all the requirements for licensure set forth in Section 4701, except passing the certification examination held by the ABGC.
- (b) A person holding a temporary genetic counselor license who fails the first available certification examination held by the ABGC may reapply, no later than 30 days after the date of the examination, on a one-time basis, for an additional temporary genetic counselor license.
- (c) A temporary license shall expire, notwithstanding subdivision (a), upon any of the following events, whichever occurs earlier:
 - (1) The issuance of a license pursuant to Section 4701.
- (2) Thirty days after notification of the board that an applicant has failed the certification examination, or on the date that the

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applicant applies and is granted an additional temporary license
pursuant to subdivision (b).

- (3) The expiration date on the temporary license.
- (d) A person holding a temporary genetic counselor license shall be required to work under the general supervision of a licensed genetic counselor or a licensed physician and surgeon.
- 4704. Fees shall be established by the board in an amount necessary to implement the provisions of this chapter. The fee for an original license and for license renewal shall not exceed two hundred dollars (\$200). All fees collected by the board shall be deposited in the Genetic Counselors Fund, which is hereby created in the Professions and Vocations Fund. Notwithstanding Section 13340 of the Government Code, the moneys in the fund shall be continuously appropriated to the board to carry out this chapter.
- SEC. 2. Section 124980 of the Health and Safety Code is amended to read:
- 124980. The director shall establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety. Regulations adopted shall implement the principles established in this section. These principles shall include, but not be limited to, the following:
- (a) The public, especially communities and groups particularly affected by programs on hereditary disorders, should be consulted before any regulations and standards are adopted by the department.
- (b) The incidence, severity, and treatment costs of each hereditary disorder and its perceived burden by the affected community should be considered and, where appropriate, state and national experts in the medical, psychological, ethical, social, and economic effects or programs for the detection and management of hereditary disorders shall be consulted by the department.
- (c) Information on the operation of all programs on hereditary disorders within the state, except for confidential information obtained from participants in the programs, shall be open and freely available to the public.
- (d) Clinical testing procedures established for use in programs, facilities, and projects shall be accurate, provide maximum information, and the testing procedures selected shall produce results that are subject to minimum misinterpretation.

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(e) No test or tests may be performed on any minor over the objection of the minor's parents or guardian, nor may any tests be performed unless the parent or guardian is fully informed of the purposes of testing for hereditary disorders and is given reasonable opportunity to object to the testing.

- (f) No testing, except initial screening for phenylketonuria (PKU) and other diseases that may be added to the newborn screening program, shall require mandatory participation, and no testing programs shall require restriction of childbearing, and participation in a testing program shall not be a prerequisite to eligibility for, or receipt of, any other service or assistance from, or to participate in, any other program, except where necessary to determine eligibility for further programs of diagnoses of or therapy for hereditary conditions.
- (g) Pretest and posttest counseling services for hereditary disorders shall be available through the program or a referral source for all persons determined to be or who believe themselves to be at risk for a hereditary disorder. Genetic counseling shall be provided by a physician, a certified advanced practice nurse with a genetics specialty, a licensed genetic counselor, or other appropriately trained licensed health care professional and shall be nondirective, shall emphasize informing the client, and shall not require restriction of childbearing.
- (h) All participants in programs on hereditary disorders shall be protected from undue physical and mental harm, and except for initial screening for phenylketonuria (PKU) and other diseases that may be added to newborn screening programs, shall be informed of the nature of risks involved in participation in the programs, and those determined to be affected with genetic disease shall be informed of the nature, and where possible the cost, of available therapies or maintenance programs, and shall be informed of the possible benefits and risks associated with these therapies and programs.
- (i) All testing results and personal information generated from hereditary disorders programs shall be made available to an individual over 18 years of age, or to the individual's parent or guardian. If the individual is a minor or incompetent, all testing results that have positively determined the individual to either have, or be a carrier of, a hereditary disorder shall be given through a physician or other source of health care.

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(i) All testing results and personal information from hereditary disorders programs obtained from any individual, or from specimens from any individual, shall be held confidential and be considered a confidential medical record except for information that the individual, parent, or guardian consents to be released, provided that the individual is first fully informed of the scope of the information requested to be released, of all of the risks, benefits, and purposes for the release, and of the identity of those to whom the information will be released or made available, except for data compiled without reference to the identity of any individual, and except for research purposes, provided that pursuant to Subpart A (commencing with Section 46.101) of Part 46 of Title 45 of the Code of Federal Regulations entitled "Basic HHS Policy for Protection of Human Subjects," the research has first been reviewed and approved by an institutional review board that certifies the approval to the custodian of the information and further certifies that in its judgment the information is of such potentially substantial public health value that modification of the requirement for legally effective prior informed consent of the individual is ethically justifiable.

- (k) A physician providing information to patients on expanded newborn screening shall disclose to the parent the physician's financial interest, if any, in the laboratory to which the patient is being referred.
- (1) An individual whose confidentiality has been breached as a result of any violation of the provisions of the Hereditary Disorders Act, as defined in subdivision (b) of Section 27, may recover compensatory and civil damages. Any person who negligently breaches the confidentiality of an individual tested under this article shall be subject to civil damages of not more than ten thousand dollars (\$10,000), reasonable attorney's fees, and the costs of litigation. Any person who knowingly breaches the confidentiality of an individual tested under this article shall be subject to payment of compensatory damages, and in addition, may be subject to civil damages of fifty thousand dollars (\$50,000), reasonable attorney's fees, and the costs of litigation, or imprisonment in the county jail of not more than one year. If the offense is committed under false pretenses, the person may be subject to a fine of not more than one hundred thousand dollars (\$100,000), imprisonment in the county jail of not more than one year, or both. If the offense is committed

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with the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, the person may be subject to a fine of not more than two hundred fifty thousand dollars (\$250,000), imprisonment in the county jail of not more than one year, or both.

- (m) "Genetic counseling" as used in this section shall not include communications that occur between patients and appropriately trained and competent licensed health care professionals, such as physicians, registered nurses, and physicians assistants who are operating within the scope of their license and qualifications as defined by their licensing authority.
- SEC. 3. Section 124981 of the Health and Safety Code is repealed.
- SEC. 4. Section 124996 of the Health and Safety Code is amended to read:
- 124996. (a) The Genetic Disease Testing Fund is continued in existence as a special fund in the State Treasury. The department may charge a fee for any activities carried out pursuant to the Hereditary Disorders Act. All moneys collected by the department under the act shall be deposited in the Genetic Disease Testing Fund, that is continuously appropriated to the department to carry out the purposes of the act.
- (b) It is the intent of the Legislature that the program carried out pursuant to the act be fully supported from fees collected under the act.
- (c) The director shall adopt regulations establishing the amount of fees for activities carried out pursuant to the act.
- (d) The "Hereditary Disorders Act" or "act" referred to in this section is the act described in subdivision (b) of Section 27.